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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,115	08/01/2000	Gregory I. Bohach	12136.1USWO	4351

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Merchant & Gould
P O BOX 2903
Minneapolis, MN 55402-0903

EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/555,115	Applicant(s) BOHACH, GREGORY I.	
	Examiner Mark Navarro	Art Unit 1645	

-- Th MAILING DATE of this communication appears on th cover sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-14,16-21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-14,16-21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment filed August 22, 2003 (Paper Number 18) has been received and entered. Claims 2, 4, and 15 have been canceled, and new claims 26-27 have been added. Consequently, claims 1, 3, 5-14, 16-21, and 24-27 are pending in the instant application.

Claim Objections

1. The objection of claim 25 for reciting an amino acid sequence without a corresponding SEQ ID NO: tag is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-3, 5-21, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a written description rejection. Additionally this rejection is applied to new claims 26-27.

Applicants are asserting that the written description requirement has been satisfied because the specification adequately describes sufficient structural features to clearly allow persons of ordinary skill in the art to recognize that the inventor has invented the claimed modified toxins. Applicants assert that the specification states that the staphylococcal enterotoxins A, B, C1, C2,

C3, D, E, G and H share a common structural feature of a disulfide bond not present in other enterotoxins. Applicants further assert that the disulfide bond has been shown to be important in the toxicity of mutants of SEC1. Applicants assert that the claimed toxins are all modified at the disulfide loop region and this structural feature correlates with disclosed functions of the toxins.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the written description requirement has been satisfied because the specification adequately describes sufficient structural features to clearly allow persons of ordinary skill in the art to recognize that the inventor has invented the claimed modified toxins. As stated in In re Hiniker Co., 150 F. 3d 1362, 1369, 47 USPQ2d 1523,1529 (Fed. Cir. 1998), the name of the game is the claim. One of skill in the art would need to speculate with respect to the meaning of the term "modified toxin." In re Steele, 305 F. 2d 859,862, 134 USPQ 292, 295 (CCPA 1962) in which both the Examiner and Board were wrong in relying on what at best are speculative assumptions respecting the meaning of the claims.

Second, Applicants assert that staphylococcal enterotoxins A, B, C1, C2, C3, D, E, G and H share a common structural feature of a disulfide bond not present in other enterotoxins and that the disulfide bond has been shown to be important in the toxicity of mutants of SEC1. However, Applicants are respectfully directed back to the claim language. Claim 1 recites "A modified toxin comprising..." No common structural feature is present in the recited claims, accordingly the

importance of the disulfide bond to toxicity cannot be ascribed to a claim which lacks this structural requirement in the first place.

Finally, Applicants assert that the claimed toxins are all modified at the disulfide loop region and this structural feature correlates with disclosed functions of the toxins. However, as set forth above, there is simply no structural requirement to be met by the claims. The claims recite "A modified toxin comprising a modified staphylococcal pyrogenic toxin having a disulfide loop region containing no more than 10 amino acid residues wherein toxicity is reduced in comparison to the unmodified native toxin." The closest limitation to a structure is the recitation of "a disulfide loop region containing no more than 10 amino acids" however, the claim also initially recites "a modified toxin..." Accordingly, the recited "structural limitation" can be freely modified to result in a structure of infinite possibilities. This point is abundantly clear from claim 14 which recites that the disulfide loop region is selected from the group consisting of SEQ ID NO: 9-17. Claim 14 depends on claim 1, which limits the disulfide loop region to no more than 10 amino acids. However, SEQ ID NO: 17, contains a disulfide loop region larger than 10 amino acids, resulting in necessary modification to the recited sequence, to arrive at the claimed sequence.

Claims 1, 3, 5-14, 16-21 and 24-27 recite a modified toxin, comprising a modified staphylococcal pyrogenic toxin having a disulfide loop region containing no more than 10 amino acid residues wherein toxicity is reduced in comparison to the unmodified native toxin.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a modified pyrogenic toxin comprising a disulfide loop region alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by modified toxins comprising a disulfide loop region which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in Paper Number 17, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1, 19 and 24 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase derived is withdrawn in view of Applicants amendment.

4. The rejection of claim 15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of substantially decreased toxicity is withdrawn in view of the cancellation of said claim.

5. The rejection of claims 16-19 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of at least about 100-fold/40% is withdrawn in view of Applicants amendment.

6. The rejection of claims 8, 10, 12, 14, and 20 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "amino acid position ##" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The rejection of claims 1, 3, 5-14, 16-21, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Olivers *et al* is maintained. Additionally this rejection is applied to newly added claims 26-27.

Applicants are asserting that independent claim 1 requires a "modified staphylococcal pyrogenic toxin." Claim 1 further requires that the modified toxin has toxicity that is reduced in comparison to the unmodified native toxin. Applicants conclude that since Olivera does not disclose a pyrogenic toxin and does not disclose a modified toxin with reduced toxicity, Olivera does not anticipate claim 1.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claim 1 requires a "modified staphylococcal pyrogenic toxin." This limitation has been fully addressed. The peptide disclosed by Olivera is not a staphylococcal pyrogenic toxin, accordingly it is deemed to meet the limitation of a modified staphylococcal pyrogenic toxin. No other structural requirements are recited in the claims to differentiate over the disclosure of Olivera.

Second, Applicants assert that claim 1 further requires that the modified toxin has toxicity that is reduced in comparison to the unmodified native toxin. This limitation too has been addressed. Given that the peptide disclosed by Olivera is not a staphylococcal pyrogenic toxin, its toxicity is "reduced" compared to an unmodified native staphylococcal pyrogenic toxin.

Finally, Applicants conclude that since Olivera does not disclose a pyrogenic toxin and does not disclose a modified toxin with reduced toxicity, Olivera does not anticipate claim 1. However, as set forth above, the peptide disclosed by Olivera is a "modified" pyrogenic toxin, since it is not a pyrogenic toxin. Furthermore, it naturally has reduced toxicity compared to an unmodified toxin, since it again is not a toxin in the first place. Accordingly, the molecule disclosed by Olivera meets each and every limitation of the claimed invention.

The claims are drawn to a modified toxin comprising a modified staphylococcal toxin having a disulfide loop region containing no more than 10 amino acid residues wherein toxicity is reduced in comparison to the unmodified native toxin.

Olivers *et al* (US Patent Number 5,885,780) disclose of methods for identifying and purifying small conotoxin like peptides. Olivers *et al* further set forth of purifying peptides of the formula Cys-Cys-Xaa-Xaa-Cys-Xaa-Xaa-Cys. (See abstract and SEQ ID NO: 15).

In view that the peptide disclosed by Olivers *et al* comprises a disulfide loop region containing no more than 10 amino acid residues, the disclosure of Olivers *et al* is deemed to anticipate the claimed invention.

Although the reference appears to disclose the same polypeptide claimed by applicants, the reference does not disclose the polypeptides produced from a Staphylococcal enterotoxin C1. However the purification or production of a product from a particular source does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

October 29, 2003